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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,018	09/17/2003	Robert S. Schwartz	20220-503	7950
37374	7590	02/13/2006		
			EXAMINER	
			DEAK, LESLIE R	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/666,018	SCHWARTZ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 17 September 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 17 September 2003 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/14/04, 1/27/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

**DETAILED ACTION*****Drawings***

1. The drawings are objected to because the drawings are done by hand and include unclear lines and reference numeral designations. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Double Patenting***

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude"

granted by a patent and to prevent possible harassment by multiple assignees.

See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/665,785. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims set forth limitations pertaining to diagnosing a patient with an increased pressure condition, implanting a device to control the pressure, and allowing the device to relieve the pressure condition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 8, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,254,564 to Wilk et al.

In the specification and figures, Wilk discloses the invention as claimed by applicant. In particular, Wilk discloses an implantable conduit 12 defining a lumen 8 therethrough. The conduit further comprises or holds a pressure differential member or valve 6 that allows pressure from the left ventricle to open the valve (thereby actuating the valve), allowing blood flow through to the coronary artery (see column 5, lines 28-46). Wilk further discloses that his device is capable of being implanted to provide communication between an artery and a vein, implanted within a heart wall, and the septums of the heart. (see column 3, lines 15-37).

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 6, 7, and 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,409,444 to Kensey et al in view of US 6,254564 to Wilk (as applied to claim 1 above).

In the specification and figures, Kensey discloses the invention substantially as claimed. Kensey discloses a device and method for dampening pressure fluctuations in the cardiac region by providing an implant with a balloon that expands and contracts in response to pressure fluctuations in the implant area (see column 3, lines 10-22). The device comprises an implantable member with a surface portion moveable between a first position and a second position depending on the pressure exerted upon the expandable surface portion. The device is designed to compensate for decreased elasticity of cardiac tissues in old age, preventing injury or stenosis of the tissues (see column 1, lines 23-57). Kensey fails to disclose that the device may traverse two anatomical structures, diverting pressure from one side to another.

Wilc discloses an implantable conduit 12 defining a lumen 8 therethrough. The conduit further comprises or holds a pressure differential member or valve 6 that allows pressure from the left ventricle to open the valve (thereby actuating the valve), allowing blood flow through to the coronary artery (see column 5, lines 28-46), thereby reducing the pressure in the LV, transferring the pressure to the CA. Wilk further discloses that his device is capable of being implanted to provide communication between an artery and a vein, implanted within a heart wall, and the septums of the heart. (see column 3, lines 15-37).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the device disclosed by Kensey to traverse an area between two vascular structures as disclosed by Wilk to provide pressure relief in order to mimic the elasticity of younger tissues and prevent injury or stenosis, as taught by Kensey.

With regard to applicant's method reciting the step of "diagnosing a patient having an elevated pressure condition in a body lumen," such a step is implicit in the method disclosed by Kensey. The disclosed surgical technique of implanting a device to dampen pressure fluctuations in the cardiac vasculature indicates that the patient is demonstrating a need for such relief, such as exhibiting elevated pressure. Therefore, the limitation reads on the Kensey reference.

With regard to claims 11, 12, 14, and 15, Wilk discloses that his device is capable of being implanted within the heart wall, cardiac septum, or blood vessels (which include the aorta and vena cava).

### ***Conclusion***

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

a. US 5,824,071 Nelson et al

i. Transmyocardial shunt with pressure-activated valve

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Leslie R. Deak  
Patent Examiner  
Art Unit 3761  
1 February 2006